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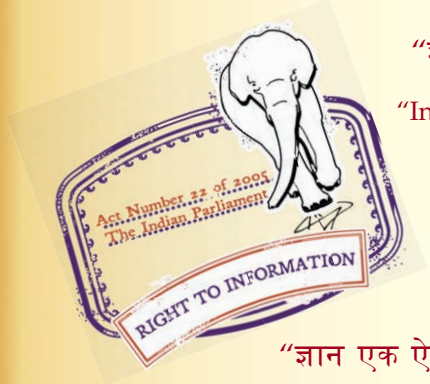
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IS 5347-15 (1997): Requirements for orthopaedic implants, Part 15: Wrought titanium 6-aluminium 7-niobium alloy [MHD 2: Orthopaedic Instruments, Implants and Accessories]



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अस्थि अन्तर्रोपणों की अपेक्षाऐं

भाग 15 पिटवां टाइटेनियम 6 -एल्यूमीनियम 7-नायोबियम मिश्रधातु

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 15 WROUGHT TITANIUM 6-ALUMINIUM 7-NIOBIUM ALLOY

ICS 11.040.40

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

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Price Group 1

NATIONAL FOREWORD

This Indian Standard (Part 15) which is identical with ISO 5832-11 : 1994 'Implants for surgery — Metallic materials — Part 11 : Wrought titanium 6-aluminium 7-niobium alloy', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards, on the recommendation of the Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Standards on basic raw materials for orthopaedic implants are covered under various parts of IS 5347. A new raw material wrought titanium 6-aluminium 7-niobium alloy has been covered in this part of the standard. Since the material is used in the manufacturing of orthopaedic implants, the publication of this part of the standard was felt necessary. This will help the Indian implants manufacturers in getting the standard material.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to an International Standard for which Indian Standard also exists. The corresponding Indian Standard which is to be substituted in its place is listed below along with its degree of equivalence for edition indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 6892 : 1984	IS 1608 : 1995 Mechanical testing of metals — Tensile testing (*second revision*)	Technically Equivalent

This Indian Standard has been issued in 15 parts. Other parts of this standard are:

Part 1	General requirements
Part 2	Wrought stainless steel
Part 3	Unalloyed titanium
Part 4	Wrought titanium 6-aluminium 4-vanadium alloy
Part 5	Cobalt-chromium-molybdenum casting alloy
Part 6	Wrought cobalt-chromium-tungsten-nickel alloy
Part 7	Wrought cobalt-nickel chromium-molybdenum alloy
Part 8	Forgeable and cold-formed-cobalt-chromium-nickel-molybdenum-iron alloy
Part 9	Ceramic materials based on alumina
Part 10	Ultra-high molecular weight polyethylene, powder form
Part 11	Ultra-high molecular weight polyethylene, moulded form
Part 12	Wrought cobalt-nickel-chromium molybdenum iron alloy
Part 13	Wrought high nitrogen stainless steel
Part 14	Wrought titanium 5-aluminium 2, 5-iron alloy

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 15 WROUGHT TITANIUM 6-ALUMINIUM 7-NIOBIUM ALLOY

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 7-niobium alloy (titanium 6-Al 7-Nb) for use in the manufacture of surgical implants.

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892:1984, *Metallic materials — Tensile testing.*

Publication ETTC 2,[1] *Microstructural standards for $\alpha + \beta$ titanium alloy bars, 1979.*[2]

3 Chemical composition

The heat analysis shall conform to the requirements as to the chemical composition prescribed in table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen, which shall be determined after the heat treatment and pickling procedure.

Table 1

Element	Compositional limits % (*m/m*)
Aluminium	5,5 to 6,5
Niobium	6,5 to 7,5
Tantalum	0,50 max.
Iron	0,25 max.
Oxygen	0,20 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,009 max.
Titanium	Balance

1) European Titanium Producers Technical Committee (ETTC).

2) Available from:

Cézus, usine d'Ugine, BP 33, 73400 Ugine, France;
Deutsche Titan GmbH, Essen, Germany;
IMI — Titanium Ltd., Birmingham, United Kingdom.

4 Microstructure

The microstructure, when examined as indicated in table 3, shall be alpha + beta, and shall correspond to photomicrographs A1 to A9 in publication ETTC 2 for annealed material.

5 Mechanical properties

The tensile properties of the alloy, determined as specified in clause 6, shall be in accordance with the requirements of table 2.

Should any of the test pieces not meet the specified requirements or should they break outside the gauge limits, two further test pieces representative of the same batch shall be tested in the same manner. The alloy shall be deemed to comply only if both additional test pieces meet the specified requirements.

If any of the retests fail to meet the appropriate requirements, the product represented shall be deemed not to comply with this part of ISO 5832.

However, the manufacturer may, if he so desires, reheat-treat the material and resubmit it for testing in accordance with the requirements of this part of ISO 5832.

6 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5832 shall be those given in table 3.

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with the provisions of ISO 6892.

Table 2 — Mechanical properties of alloy in annealed condition

Form of alloy	Tensile strength min. MPa	Proof stress of non-proportional elongation min. MPa	Percentage elongation min. %	Reduction of area min. %
Bar[1)]	900	800	10	25
1) Maximum diameter or thickness = 100 mm				

Table 3 — Test methods

Requirement	Relevant clause	Test methods
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Microstructure	4	ETTC 2
Mechanical properties	5	
Tensile strength		ISO 6892
Proof stress of non-proportional elongation		ISO 6892
Percentage elongation		ISO 6892
Reduction of area		ISO 6892

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'.

This Indian Standard has been developed from Doc: No. MHD 2 (2699).

Amendments Issued Since Publication

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